Patent Claims

5

- 1. Process for the preparation of storage-stable, multiple emulsions of the water/oil/water (W/O/W) type which comprise one or more active ingredients with the steps
 - a) stirring the active ingredient into an aqueous phase,
 - b) emulsifying the aqueous phase by passing the aqueous phase through a large-pored, porous membrane into an oil phase,
- phase inversion of the emulsion from b), by cooling the mixture at a cooling rate of at least 0.3 K/min, where an emulsifier is added either to the aqueous phase in a) or to the oil phase in b) or to both phases.
- 2. Process according to Claim 1, characterized in that the membrane used is a porous inorganic membrane, preferably ceramic membrane, particularly preferably membranes of aluminium oxide, zirconium oxide or titanium oxide, preferably of aluminium oxide.
- 3. Process according to Claims 1 to 2, characterized in that the pore size of the membrane used is 0.2 to 5 μm, preferably 0.3 to 3 μm.
 - 4. Process according to one of Claims 1 to 3, characterized in that the oil used for the oil phase is a substance chosen from the series mineral oil, white oil or vegetable oil.

5. Process according to one of Claims 1 to 4, characterized in that the emulsifier used is a nonionic emulsifier which is initially introduced in the oil phase.

6. Process according to one of Claims 1 to 5, characterized in that the emulsification in step a) is carried out at a temperature of from 30 to 35°C.

W SM1 141098 v1

25

- 7. Process according to one of Claims 1 to 6, characterized in that the phase inversion according to step c) is carried out at a cooling rate of at least 1 K/min.
- Process according to one of Claims 1 to 7, characterized in that the pressure difference over the membrane is $0.5*10^5$ Pa to $25*10^5$ Pa, preferably $0.15*10^5$ Pa to $5*10^5$ Pa.
- 9. Process according to one of Claims 1 to 8, characterized in that the process is carried out continuously in all steps.
 - 10. Process according to one of Claims 1 to 9, characterized in that the active ingredient is a pharmaceutical active ingredient, preferably a pharmaceutical active ingredient for veterinary purposes, particularly preferably an antigen for a vaccine formulation.
- 11. Process according to Claim 10, characterized in that the active ingredient is chosen from the series comprising an antigen, preferably a virus or a microorganism, in particular a bacterium or parasite, or a preparation which comprises a peptide chain, preferably a protein or a glycoprotein, particularly preferably a protein or a glycoprotein which has been obtained from a microorganism, a synthetic peptide or a protein or peptides which has been prepared by genetic manipulation.
- Multiple emulsion of the W/O/W type obtainable from a process according to one of Claims 1 to 11.
 - 13. Use of the emulsion according to Claim 12 as vaccine for human or veterinary medical purposes.

15